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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,422	08/10/2001	Gary Van Nest	377882001420	6952

25226 7590 12/24/2003

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/24/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/927,422	Applicant(s) NEST ET AL.	
	Examiner N. M. Minnifield	Art Unit 1645	

-- The MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *24-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23 and 48-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 3 sheets
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-23 and 48-84, in Paper No. 16 is acknowledged.

2. Claims 24-47 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 16.

3. Applicants should update the status of related applications; 09/802359 is abandoned.

4. The disclosure (see for example page 41) is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-23 and 48-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, 18-22, 27-29 and 51-62 of copending Application No. 10/214799. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claimed a complex comprising an IMP/MC, immunomodulatory polynucleotide (or oligonucleotide) and a microcarrier, covalently or non-covalently linked, as well as claims to a kit comprising said complex. The complex can also comprise an antigen. The microcarrier can be a liquid phase or solid phase microcarrier. The IMP can vary in length and can comprise a phosphate backbone modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-21, 48-67, 70-78 and 81-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most

nearly connected, to make and/or use the invention. The claims are directed to a IMP/MC complex that comprises a polynucleotide (sequence 5'-C, G-3') linked to a microcarrier and may comprise an antigen (i.e. allergen). The specification contemplates that the claimed invention would be used as a pharmaceutical or therapeutic composition for in vivo use (see pp. 9-20; pp. 35-42; Table 1) in humans or animals. However, all the examples set forth in the specification are *in vitro* assays. The specification does not enable the claims wherein the polynucleotide is sequence 5'-C, G-3' for example. The state of the art indicates that these "oligonucleotides in their natural phosphodiester form are subject to rapid degradation in the blood or intracellular fluid by exonucleases and endonucleases. Since the half-life of phosphodiester oligonucleotides is typically only 15-60 min in blood and tissue-culture media, they are not attractive drug candidates." (Plenat, Molecular Medicine Today, 1996, 1:250-257, see p. 250). It would require a phosphorothioate backbone to avoid degradation of the motif when administered to an individual. The specification has not enabled the claimed invention and in view of the state of the art it would require undue experimentation to use the claimed invention.

8. Claims 1-23 and 48-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 48-84 appear to be of the same scope as claims 1-23. The components are exactly the same; are there any instructions for use of the kit as a diagnostic composition or a pharmaceutical composition. The claims are vague and indefinite in the recitation of "5'-C, G-3'"; what does Applicant intend? How long is this polynucleotide

sequence? Claim 13 lacks positive antecedent basis in the recitation of "5'-TCGTCGX$_1$-3'"; this is not one of the sequences of claim 12.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-23 and 48-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Carson et al (WO 98/16247), Ray (WO 99/11275) or Schwartz et al (WO 98/55495).

The claims are directed to a IMP/MC complex that comprises a polynucleotide (sequence 5'-C, G-3') linked (non-covalently or covalently) to a microcarrier and may comprise an antigen (i.e. allergen). The MC is a liquid phase or solid phase or cationic and is less than 10 microns in size. The

polynucleotide may be SEQ ID NO: 1 or have a phosphate backbone modification (phosphorothioate).

Schwartz et al, for example, discloses a complex that comprises an oligonucleotide in conjunction with an immunostimulatory peptide or antigen (abstract; p. 4). The prior art discloses that the complex can also comprise an encapsulating agent that can maintain the ISS and antigen (pp. 7-8; p. 13). Schwartz et al discloses that the oligonucleotides (i.e. ISS or IMP) comprise phosphorothioate backbones, which are phosphate backbone modifications (p. 11; p. 29). Schwartz et al discloses that the oligonucleotide can be combined with immunomodulatory facilitators such as adjuvants, such adjuvants include emulsions and polylactide/polyglycolide microparticles (i.e. MC) (p. 12, 14; claims). Schwartz et al discloses that the ISS can be covalently or non-covalently linked to the immunomodulatory facilitator (i.e. MC) (p. 14). The prior art discloses the nucleotide sequence as set forth in Applicants' SEQ ID NO: 1 (see SEQ ID NO: 15). It is noted that claims 48-84 are directed to a kit. The components of the kit are the same as the components of claims 1-23 and it would appear that Schwartz et al would disclose the claimed kit. Determining the size of the microparticle would have been within the knowledge of a skilled since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Since the Patent Office does not have the facilities for examining and comparing applicants' complex and kit with the complex and kit of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed complex and kit and the

complex and kit of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

12. Claims 1-23 and 48-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Raz et al (6534062) or Friede et al (6544518).

Raz et al, for example, discloses an immunostimulatory nucleic acid molecule (i.e. IMP) prepared in a pharmaceutically acceptable carrier such as a sterile aqueous or non-aqueous solution, suspension and emulsions (col. 24-26). The aqueous carriers include emulsions, suspensions and microparticles (i.e. MC). Raz et al discloses that use of antigens in the complex (col. 27; cols 7-10). The prior art discloses the nucleotide sequence as set forth in Applicants' SEQ ID NO: 1 (see SEQ ID NO: 1 of the patent SEQUENCE LISTING). It is noted that claims 48-84 are directed to a kit. The components of the kit are the same as the components of claims 1-23 and it would appear that Schwartz et al would disclose the claimed kit. . Determining the size of the microparticle would have been within the knowledge of a skilled since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Since the Patent Office does not have the facilities for examining and comparing applicants' complex and kit with the complex and kit of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed complex and kit and the complex and kit of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

13. No claims are allowed.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
December 11, 2003